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10/615,695	07/08/2003	Hsu-Shan Huang	HUAH104	9695

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EXAMINER

BADIO, BARBARA P

ART UNIT PAPER NUMBER

1617

DATE MAILED: 11/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/615,695	Applicant(s) HUANG, HSU-SHAN	
	Examiner Barbara P. Badio, Ph.D.	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/2003; 03/2005</u> . | 6) <input type="checkbox"/> Other: ____. |

First Office Action on the Merits

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims recite 1,4,5,8-tetrasubstituted anthraquinones of formula 1. However, the present specification does not convey to the skilled artisan in the art that applicant, at the time the application was filed, had possession of said compounds because it discloses **bis-substituted** and not **tetra-substituted** anthraquinone derivatives as encompassed by the instant claims. The present specification does not teach how to make and use the instantly claimed invention as required under 35 USC 112, first paragraph.

With regards to claims 13-18, the present specification fails to provide sufficient descriptive information, such as correlation of the various effects such as inhibition of cellular growth, enhancement of lipid peroxidation etc. and treatment of a representative number of diseases and, thus, it lacks adequate description of the

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presently claimed invention. In other words, the present specification does not reasonably convey to the skilled artisan in the art that at the time of the present application, applicant had possession of the claimed invention. Adequate written description requires more than a mere indication that the claimed compound(s) have certain effect(s). Some correlation between said effect(s) and treatment of a representative number of diseases is required.

3. Claims 13-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are (1) the nature of the invention, (2) the breadth of the claims, (3) the state of the prior art, (4) the predictability or unpredictability of the art, (5) the amount of guidance or direction presented, (6) the presence or absence of working examples, (7) the relative skill in the art and (8) the quantity of experimentation necessary. When the above factors are taken into consideration, the examiner's position is that one skilled in the art could not perform the invention commensurate in scope with the instant claim without undue experimentation.

The instant claims are drawn to treatment of cancers, treatment of abnormal proliferation, enhancing anti-oxidation effect, enhancing human telomerase activity, stem cell research or enhancing tissue-engineering application by administering the claimed compound(s). The instant claims lack recitation of specific diseases and, thus, read on all diseases, known and unknown, that might be treatable utilizing the claimed anthraquinone derivatives. The art lacks treatment of the vast number of the diseases encompassed by the instant claims utilizing a single agent. For example, the art does not teach treatment of all cancers utilizing a single agent.

The present specification discloses different effects of the claimed compound(s) such as cytotoxicity, effect on lipid peroxidation, telomerase activity etc. However, there is no showing that said effects would result in treatment of any disease and, thus, there is insufficient guidance for the skilled artisan to be able to utilize the claimed compounds in the treatment of the scope of diseases encompassed by the instant claims. The amount of experimentation necessary to practice the claimed invention commensurate in scope with the instant claims would not be routine because the skilled artisan would have to first determine the effect of oxidation, telomerase activity etc. in the development of each disease, known and unknown, before determining the effect of the claimed compounds on the treatment of said diseases. Said determination would result in undue experimentation.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claims fail(s) to correspond in scope with that which applicant(s) regard as the invention can be found in the specification filed July 8, 2003. In the originally filed specification, applicant has stated that the claimed compounds are bis-substituted anthraquinone derivatives, and this statement indicates that the invention is different from what is defined in the claim(s) because the compounds encompassed by the instant claims are tetra-substituted and not bis-substituted anthraquinone derivatives.

6. Claims 1-9 and 13-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite for the following reasons:

(a) Claim 1, identifies but does not define "n";

(b) Claim 1 recites two sets of definition for R1-R4. Does applicant intend the combination of the groups defined by said definitions or the utilization of one or the other definition?

(c) Claim 1 recites various incomplete groups. For example, (i) $-(CH_2)_nNH$ (nitrogen has two instead of three attachments) or (ii) $-S-$, $-OCO-$, $-N-$ etc. These groups do not define a complete substituent and, thus, it is unclear what is intended.

(d) Claims 2 and 3 recite groups, for example, ethylphenyl, $2-OH-C_6H_4$, $CH_2Br(Cl)$ and CH_2OH , not encompassed by parent claim 1.

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(e) Claims 13-18 recite various methods comprising administering the claimed compound(s) to a patient in need of "such" treatment. However, the instant claims lack identification of disease(s) that said patient has that would require the administration of the claimed compound(s). Therefore, the metes and bound of the claimed invention is indefinite.

Duplicate Claims

7. Claims 4-9 and 19-25 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 1 and 11, respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Note: The recitation of the intended use does not further limit the parent claims.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 4-9, 11 and 19-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Allen et al. (US 2,611,772).

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Allen et al. teaches 1,4,5,8-tetraamino-anthraquinones such as 1,4,5,8-tetrahydroxyethylaminoanthraquinone (see the entire article, especially col. 2, line 25-26). The compounds taught by the reference are encompassed by the instant claims.

10. Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Patterson (US 5,132,327).

Patterson et al. teaches the production of bis-substituted anthraquinones by reacting the corresponding 1,5-dichloroanthraquinone or 1,8-dichloroanthraquinone with an amine (see the entire article, especially Examples 1(1) and 4(1)). The process taught by the reference is encompassed by the instant claim.

Note: Where the steps of a process are the same as the prior art, and the only difference is in the recital of the product produces, the process may properly be rejected as anticipated (*In re Sussman*, 141 F.2d 267).


Telephone Inquiry

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Barbara P. Badie, Ph.D.
Primary Examiner
Art Unit 1617

BB

November 16, 2005